Laboratory Testing for Initial Assessment and Monitoring While on Antiretroviral Therapy

(Updated January 10, 2011)

A number of laboratory tests are important for initial evaluation of HIV-infected patients upon entry into care, during follow-up if antiretroviral therapy (ART) has not been initiated, and prior to and after initiation or modification of therapy to assess virologic and immunologic efficacy of ART and to monitor for laboratory abnormalities that may be associated with antiretroviral (ARV) drugs. <u>Table 3</u> outlines the Panel's recommendations for the frequency of testing. As noted in the table, some of the tests may be repeated more frequently if clinically indicated.

Two surrogate markers are used routinely to assess the immune function and level of HIV viremia: CD4 T-cell count (CD4 count) and plasma HIV RNA (viral load). Resistance testing should be used to guide selection of an ARV regimen in both ART-naïve and ART-experienced patients; a viral tropism assay should be performed prior to initiation of a CCR5 antagonist; and HLA-B*5701 testing should be performed prior to initiation of abacavir (ABC). The rationale and utility of these laboratory tests are discussed below.

Table 3. Laboratory Monitoring Schedule for Patients Prior to and After Initiation of **Antiretroviral Therapy** (Updated January 10, 2011)

	Entry into care	Follow- up before ART	ART initiation or modification ¹	2–8 weeks post-ART initiation or modification	Every 3–6 months	Every 6 months	Every 12 months	Treatment failure	Clinically indicated
CD4 count	√ 	every 3–6 months	V		√	In clinically stable patients with suppressed viral load, CD4 count can be monitored every 6–12 months (see text)		√ 	V
Viral load	V	every 3–6 months	V	$\sqrt{2}$	$\sqrt{3}$			V	V
Resistance testing	V		$\sqrt{4}$					V	V
HLA-B*5701 testing			√ if considering ABC						
Tropism testing			√ if considering a CCR5 antagonist					if considering a CCR5 antagonist or for failure of CCR5 antagonist-based regimen	√
Hepatitis B serology ⁵	√ 		may repeat if HBsAg (-) and HBsAb (-) at baseline						V
Basic chemistry ⁶	V	every 6–12 months	$\sqrt{}$	V	V				V
ALT, AST, T. bilirubin	V	every 6–12 months	V	V	1				V
CBC with differential	V	every 3–6 months	V	√ if on ZDV	1				V
Fasting lipid profile	V	if normal, annually	V	consider 4–8 weeks after starting new ART		if abnormal at last measurement	if normal at last measurement		V
Fasting glucose	V	if normal, annually	V		if abnormal at last measurement	√ if normal at last measurement			V
Urinalysis ⁷	V		V			$\sqrt{\frac{1}{\text{if on TDF}^8}}$	√		V
Pregnancy test			√ if starting EFV						V

¹ARV modification may be done for treatment failure, adverse effects, or simplification.

Acronyms: 3TC = lamivudine, ABC = abacavir, ALT = alanine aminotransferase, ART = antiretroviral therapy, AST = aspartate aminotranserase, CBC = complete blood count, EFV = efavirenz, FTC = emtricitabine, HBsAb = hepatitis B surface antibody, HBsAg = hepatitis B surface antigen, HBV = hepatitis B virus, MDRD = modification of diet in renal disease (equation), TDF = tenofovir, ZDV = zidovudine

References

Gupta SK, Eustace JA, Winston JA, et al. Guidelines for the management of chronic kidney disease in HIV-infected patients: 1. recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis. 2005;40(11):1559-1585.

²If HIV RNA is detectable at 2–8 weeks, repeat every 4–8 weeks until suppression to <200 copies/mL, then every 3–6 months.

For adherent patients with suppressed viral load and stable clinical and immunologic status for >2-3 years, some experts may extend the interval for HIV RNA monitoring to every 6 months.

⁴For ART-naïve patients, if resistance testing was performed at entry into care, repeat testing is optional; for patients with viral suppression who are switching therapy for toxicity or convenience, resistance testing will not be possible and therefore is not necessary.

5 If HBsAg is positive at baseline or prior to initiation of ART, TDF + (FTC or 3TC) should be used as part of ARV regimen to treat both HBV and HIV infections. If HBsAg and

HBsAb are negative at baseline, hepatitis B vaccine series should be administered.

⁶ Serum Na, K, HCO₃, Cl, BUN, creatinine, glucose (preferably fasting); some experts suggest monitoring phosphorus while on TDF; determination of renal function should include estimation of creatinine clearance using Cockcroft-Gault equation or estimation of glomerular filtration rate based on MDRD equation.

⁷For patients with renal disease, consult "Guidelines for the Management of Chronic Kidney Disease in HIV-Infected Patients: Recommendations of the HIV Medicine Association of the Infectious Diseases Society of America" [1].

⁸ More frequent monitoring may be indicated for patients with increased risk of renal insufficiency, such as patients with diabetes, hypertension, etc.